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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,591	07/10/2000	William J. Boyle	A-378CIP5	9711

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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 02/22/2002

→ 3

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/613,591

Applicant(s)

BOYLE ET AL.

Examiner

Regina M. DeBerry

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a method for treating conditions leading to bone loss which comprises administering isolated OPG and IL-1 inhibitors, classified in class 514, subclass 2.
- II. Claims 1,6-13, drawn to a method for treating conditions leading to bone loss which comprises administering isolated OPG and TNF- $\alpha$  inhibitor, classified in class 512, subclass 2.
- III. Claims 1,14-16, drawn to a method for treating conditions leading to bone loss which comprises administering isolated OPG and a serine protease inhibitor, classified in class 514, subclass 2.
- IV. Claims 1, 17-25, 32, 39-42, drawn to a method for treating conditions leading to bone loss which comprises administering isolated OPG, IL-1 inhibitor and TNF- $\alpha$  inhibitor, classified in class 514, subclass 2.
- V. Claims 1, 26-29, 39-42, drawn to a method for treating conditions leading to bone loss which comprises administering isolated OPG, IL-1 inhibitor and a serine protease, classified in class 514, subclass 2.
- VI. Claims 1, 30,31,33-42, drawn to a method for treating conditions leading to bone loss which comprises administering isolated OPG, serine protease inhibitor and TNF- $\alpha$  inhibitor, classified in class 514, subclass 2.

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- VII. Claims 43-48, drawn to a method of treating an IL-1 mediated disease which comprises administering therapeutically effective amounts of an IL-1 inhibitor and a serine protease inhibitor, classified in class 514, subclass 2.
- VIII. Claims 49-57, drawn to a method of treating TNF-mediated disease which comprises administering therapeutically effective amounts of a TNF- $\alpha$  inhibitor and a serine protease inhibitor, classified in class 514, subclass 2.
- IX. Claims 58-59, drawn to a method of treating inflammation, classified in class 514, subclass 2.
- X. Claim 60, drawn to a method of treating SLE which comprises administering an IL-18 inhibitor, TNF- $\alpha$  inhibitor and an IL-1 inhibitor, classified in class 514, subclass 2.
- XI. Claim 61, drawn to a method of treating GvHD which comprises administering an IL-18 inhibitor, TNF- $\alpha$  inhibitor and an IL-1 inhibitor, classified in class 514, subclass 2.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-XI are directed to methods that recite structurally and functionally distinct elements, are not

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required one for the other, and/or achieve different goals. The Inventions are drawn to a methods for treating a wide range of conditions such as conditions leading to bone loss while other Inventions are drawn to methods of treating graft versus host disease, IL-1 or TNF mediated diseases. The Inventions also require search and consideration of efficacy of treatment comprising administering various combinations of OPG, IL-1 inhibitor, serine protease inhibitor and TNF- $\alpha$  inhibitor. Therefore, a search and examination of all methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD

RMD

February 20, 2002

Elizabeth C. Semmes

ELIZABETH KEMMERS  
PRIMARY EXAMINER